REMARKS

INTRODUCTORY MATTERS

Claims 6-9 are pending in this application. Claims 1-5 and 10-19 are withdrawn and claims 20 and 21 are canceled. Following entry of this amendment, claims 6-9 will be pending.

Applicants acknowledge, with thanks, the Examiner's withdrawal of the objection to the specification and the rejections under 35 U.S.C. §§ 102(b) and 112, first paragraph.

THE CLAIM AMENDMENTS

Applicants have amended claim 6 to specify the amino acid sequence of the finger 1, finger and heel subdomains of OP-1.

Applicants have amended claims 8 and 9 to improve their form.

None of the amendments introduces any new matter.

THE REJECTIONS

35 U.S.C. § 102(e)

The Examiner has maintained the rejection of claims 6-8 under 35 U.S.C. § 102(e) as being anticipated by Nimni et al., U.S. Patent No. 6,352,972 ("Nimni"). The Examiner contends that Nimni teaches a TGF-β fusion protein comprising a TGF-β1 active fragment and a leader sequence, which may comprise a purification tag, proteinase sensitive linker sites and a protein binding domain. The Examiner further states that Nimni teaches that the refolded fusion protein under low concentrations of urea and DTT or a redox system using DTT in conjunction with glutathione had little biological activity. The Examiner also states that Nimni teaches a fusion protein comprising the active portion of BMP proteins such as OP-1.

The Examiner concludes that since the fusion protein appears to satisfy the structural requirement, the additional properties recited in claims 6-8 are inherent to the structure of the fusion protein.

The Examiner also alleges that the instant claims are drawn to a genus of OP-1 fusion proteins and are not limited to specific OP-1 proteins. The Examiner alleges that because Nimni teaches a fusion protein comprising OP-1, the teachings of Nimni meet the limitations of the claims of the instant application. The Examiner further alleges that Nimni teaches that the activities of the refolded protein depend upon the refolding conditions.[1] The Examiner concludes that whether a refolded TGF-β fusion protein is active or not depends not only upon the leader sequence, but also the refolding conditions and the formation of homodimers or heterodimers.

Applicants traverse. However, solely to expedite prosecution of this application, applicants have amended the claims of the instant application to recite a latent OP-1 fusion protein comprising specific OP-1 finger 1, finger 2 and heel subdomain sequences. Nowhere in Nimni is there any recitation of fusion proteins comprising such OP-1 sequences. Accordingly, Nimni does not anticipate the amended claims of the instant application and applicants request that the Examiner withdraw the novelty rejection.

[1] Throughout the rejection set forth on pages 3-5 of the Office Action, the Examiner refers to Hall (WO96/39430) and cites to examples and pages from Hall, not Nimni.

CONCLUSION

In view of the foregoing remarks and amendments, applicants request that the Examiner favorably reconsider this application and allow the amended claims pending therein. Should the Examiner feel that a telephone conference with applicants' representatives would assist the Examiner, she is invited to telephone the undersigned at any time.

Respectfully submitted,

/ KAREN MANGASARIAN /

James F. Haley, Jr. (Reg. No. 27,794)
Karen Mangasarian (Reg. No. 43,772)
Attorneys for Applicants

ROPES & GRAY LLP
Customer No. 1473
1211 Avenue of the Americas
New York, New York 10036
Tel.: (212) 596-9000
Fax: (212) 596-9090